REMARKS

Claims 83, 84 and 87 are currently pending. Claim 83 has been amended to remove the "improper internal periods". Claim 84 has been amended to remove what the Examiner considers to be new matter.

The Office Action dated June 7, 2005, has been carefully reviewed and the following remarks are made in response thereto. In view of these remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Objection

Claim 83 has been objected to as allegedly containing "improper internal periods". Applicants have amended the claim to remove the periods. The Examiner is respectfully requested to withdraw this objection.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 84 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement in that the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action alleges that the phrase "from one or more of the group..." is considered to be new matter.

Without acquiescing to the rejection and in an effort to move prosecution forward, Applicants have amended claim 84 to replace the phrase "wherein the characterized biosystem is selected from one or more of the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays" to "wherein the characterized biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays".

Currently pending claim 84 as newly amended reads as follows:

> "The method of claim 83, wherein the characterized biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays."

Originally-filed claim 21 reads as follows:

> "The method of claim 1, 11, 12, 13, 17 or 18, wherein the biosystem is selected from the group consisting of cells, tissues, organs, whole organisms and *in vitro* assays."

Thus, the newly added phrase "is selected from the group consisting of" finds explicit literal support at least in claim 21 of the as-filed specification. Therefore, the Examiner is respectfully requested to withdraw this rejection.

Rejections under 35 U.S.C. § 102(e)(2)

Claims 83, 84 and 87 are rejected under 35 U.S.C. § 102(e)(2) as allegedly being clearly anticipated by Khwaja *et al.* (U.S. Patent No. 6,113,907). The Office Action asserts that the disclosure of Khwaja et al. "has been reasonably construed as the claimed HBR Array" (Office Action ¶ 11, last line and ¶ 12, last line).

In order for a reference to be "anticipatory" under 35 U.S.C. § 102(e)(2), "the reference must teach every aspect of the claimed invention either explicitly or impliedly" and "any feature not directly taught must be inherently present" (M.P.E.P. § 706.02, underlining added). Thus, the standard for applying a reference as anticipatory prior art is not "reasonably construed" as suggested twice by the Examiner in the latest Office Action. The Examiner is respectfully requested to provide the statutory or regulatory basis upon which the "reasonably construed" standard is based.

A reading of claim 83 quickly verifies the importance of gene expression profiles to the claimed method (underlining added for emphasis):

"83. A quality control method for assessing the equivalency of a test batch of an herbal composition to a standardized batch of the same or substantially same herbal composition, wherein the herbal composition comprises multiple chemical components derived from one or more whole plants or plant parts, said quality control method comprising:

(a) selecting a preparation of an herbal composition to be the standardized batch;

(b) characterizing an Herbal BioResponse (HBR) Array for the standardized batch by

> (i) exposing a characterized biosystem to the standardized batch, determining a differential gene expression profile as compared with an untreated control of the characterized biosystem, and obtaining an array of gene expression changes for two or more molecular markers for the standardized batch; and

(ii) storing the array of gene expression changes obtained in step (b)(i) into a Standardized HBR Array;

(c) characterizing an Herbal BioResponse (HBR) Array for the test batch by

(i) exposing the characterized biosystem used in step (b)(i) to the test batch, determining the differential gene expression profile compared with an untreated control of the characterized biosystem, and obtaining an array of gene expression changes for two or more molecular markers for the test batch; and

(ii) storing the array of gene expression changes obtained in (c)(i) into a Test HBR Array;

(d) assessing a quantitative similarity value between the Standardized HBR Array and the Test HBR Array by comparing gene expression intensities and gene expression patterns; and

utilizing the similarity value obtained in step d to assess the equivalency of the test batch and the standardized batch for the purpose of quality control."

Thus, the claimed method explicitly requires "determining a differential gene expression profile", "obtaining an array of gene expression changes", "storing the array of gene expression changes", and "comparing gene expression intensities and gene expression patterns".

In contrast, Khwaja *et al.* disclose using compositional and bioactivity fingerprints for the processing of St. John's Wort to produce botanical drugs. As stated in the previously-filed 'Declaration Under 37 C.F.R. § 1.132' executed by Dan Theodorescu, M.D., Ph.D., "the methods taught by Khwaja *et al.* do not include using gene expression profiles for quality control" (Theodorescu Declaration, page 5). In fact, Applicants could not locate a single use of the words "gene" or "genetic" anywhere within the disclosure of Khwaja *et al.* Therefore, Applicants are at a complete loss to understand how the Examiner can apply Khwaja *et al.* as an anticipatory reference when it fails to even mention or discuss the central aspects of the presently claimed invention. Merely stating that the reference is "reasonably construed" to teach the claimed invention clearly does not meet the anticipatory standard.

In view of the previously-filed response, including the extensive Theodorescu Declaration, and the claim amendments and reasons provided herein, the Examiner is respectfully requested to withdraw this rejection and allow the presently pending claims. to go to issuance.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. A favorable action is awaited. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

If there are any additional fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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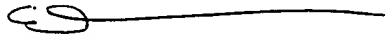

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Dated: November 7, 2005
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